Remarks:

Claims

By the present amendment claims 25, 27, 29, 31-32, 43 and 46 have been amended; and new claims 50-54 have been added to more particularly and distinctly claim the subject matter of Applicant's invention. Claims 25, 27, 29, 31-32, 43-44, 46 and 50-54 are pending.

Support for the amendments is either apparent or is described below. Support for recombinant polypeptide can be found, for example, at page 1, line 7; page 3, line 15; page 7, lines 13-15; and page 8, line 13-17. No new matter is added.

Claim Rejections - 35 U.S.C. §112, First Paragraph -Written Description

Claims 25, 27, 29, 31, 43-44 and 46 stand rejected under 35 U.S.C. §112, first paragraph based on an assertion the claims contained subject matter that was not described in the specification in such a way as to reasonably convey to one of skill in the art that the inventor, at the time the application was filed, had possession of the claimed invention. In particular, the Examiner asserted that the specification does not disclose the actual biological function of the polypeptide SEQ ID NO:2. The Examiner contended that the specification further does not a single fragment of a polypeptide having the sequence of SEQ ID NO:2, and that the skilled artisan cannot envision from the specification, the contemplated sequences of the claimed fragments. The Examiner notes that the immune response induced by immunogenic fragment of 15 or 20 contiguous amino acids of SEQ ID NO: 2 is not set forth in the claims.

While not conceding the correctness of the rejection Applicant has amended claims 25 and 27 to more particularly and distinctly define the invention. Applicant submits that the claims as amended, recite immunogenic fragments that particularly and distinctly describe the specificity of an immune response induced by the immunogenic fragments. Applicant notes that the specification discloses an immunogenic fragment of a BASB053 polypeptide, that is a contiguous portion of the BASB053 polypeptide which has the same or substantially the same immunogenic activity as the polypeptide comprising the amino acid sequence of SEQ ID NO:2 at, for example, page 5, lines 4-8. Reconsideration of the Written Description Requirement rejection under 35 U.S.C. 112, ¶1 is therefore respectfully requested.

Claim Rejections - 35 U.S.C. §112, First Paragraph - Enablement

Claims 25, 27, 29, 31, 43-44 and 46 stand rejected under 35 U.S.C. §112, first paragraph based on an assertion, that the specification, while being enabling for an isolated polypeptide consisting of the amino acid sequence SEQ ID NO: 2, and fusion protein comprising the amino acid sequence SEQ ID NO: 2, does not reasonably provide enablement for any immunogenic fragment comprising a fragment sequence of at least 15 or 20 amino acids that matches contiguous segments of SEQ ID NO:2. The Examiner contends that the skilled artisan would be forced into undue experimentation to practice the invention as broadly claimed.

The Examiner also stated that she considered the arguments of 6/12/03 but did not deem them persuasive. The Examiner asserts that the claims do not set forth that the antibody response induced by the immunogenic fragments recognizes the full length protein.

Without conceding the correctness of the rejection, Applicant has amended claims 25 and 27 to more particularly and distinctly define the invention. Applicant submits that the claims as amended, recite immunogenic fragments that particularly and distinctly describe the specificity of an immune response induced by the immunogenic fragments. It is submitted that the claims as amended are enabled. Accordingly, reconsideration of the rejection under 35 U.S.C. §112, first paragraph is respectfully requested.

Claim Rejection - 35 U.S.C. §102(b) - Martin et al.

Claims 27, 29, 38 and 43-44 stand rejected under 35 U.S.C. §102(b) based on an assertion that the claims are anticipated by Martin et al. (J. Ex. Med. Volume 185, No. 7, 1997, pp 1173-1184). In particular the Examiner asserted:

> Martin et al disclose an isolated polypeptide, outer membrane polypeptide from whole cell lysate of OM preparations from various clinical isolates including nine meningococcal strains two of serogroup A (604A and Z4063), one of serogroup B (608B [B: 2a:P1.2; L3]), two of serogroup C (2241C and 59C), one of serogroup 29-E, one of serogroup W-135, one of serogroup Y (SLATY) one of serogroup Z (SLATZ) (page 1174, under materials and method, antigens). Monoclonal antibodies were produced by immunizing mice with OM preparation indicating that the disclosed isolated polypeptides are immunogenic and thus read on claim 46. Applicant's use of the open-ended term "comprising" in the claims fails to exclude unrecited steps or ingredients and leaves the claims open for inclusion of unspecified ingredients,

> even in major amounts. Whole cell lysates prepared in buffer (pharmaceutical carrier) from N.meningitidis inherently comprise the amino acid sequence set for in the SEQ ID NO:2 and several N.meningitidis antigens. See In re Horvitz, 168 F 2d 522, 78 U.S.P.Q. 79 (C.C.P.A. 1948) and Ex parte Davis et al., 80 U.S.P.Q. 448 (PTO d. App. 1948). Since the Office does not have the facilities for examining and comparing applicants' claimed isolated polypeptide comprising SEQ ID NO: 2, with the polypeptide of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Without conceding the correctness of the rejection, Applicant has amended the claims to more particularly and distinctly claim the subject matter of his invention. It is submitted that the amended claims recite an isolated, recombinant polypeptide. The claimed isolate is not disclosed or suggested by the OMP preparations described in Martin et al.

Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. §102(b) is respectfully requested.

Amendments to the Specification:

Applicant has amended the Brief Description of the Drawings to comport with the labels submitted with the replacement drawings.

No new matter is added. Entry of the amendment to the specification into the record of the instant application is respectfully requested.

Amendments to the Drawings:

Applicant has submitted Replacement Figures to address the objections raised by the Draftsperson in Paper No. 9. Figure 1 has been relabeled as Figures 1A-1J. Figure has been relabeled as Figure 2A-2D. The title text has been removed from Figure 3.

No new matter is added. Entry of the replacement drawings into the record of the instant application is respectfully requested.

Information Disclosure Statement:

Applicant has concurrently filed an Information Disclosure Statement (IDS) listing the references cited in the International Search Report for PCT/EP00/00137 on a PTO-1449 form. It is noted that copies of the references have been received by the Office as indicated on Form PCT/DO/EO/903 (entitled, "Notification and Acceptance of Application under 35 U.S.C. 371 and 37 CFR 1.494 or 1.495"). It is respectfully requested that the listed references be included in the "References Cited" portion of any patent issuing from this application.

FEE DEFICIENCY

☒ If an extension of time is deemed required for consideration of this paper, please consider this paper to comprise a petition for such an extension of time; The Commissioner is hereby authorized to charge the fee for any such extension to Deposit Account No. 50-0258.

and/or

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Closing Remarks

Applicant thanks the Examiner for the Office Action and believe this response to be a full and complete response to such Office Action. Accordingly, favorable reconsideration in view of this response and allowance of the pending claims are earnestly solicited.

Respectfully submitted,

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